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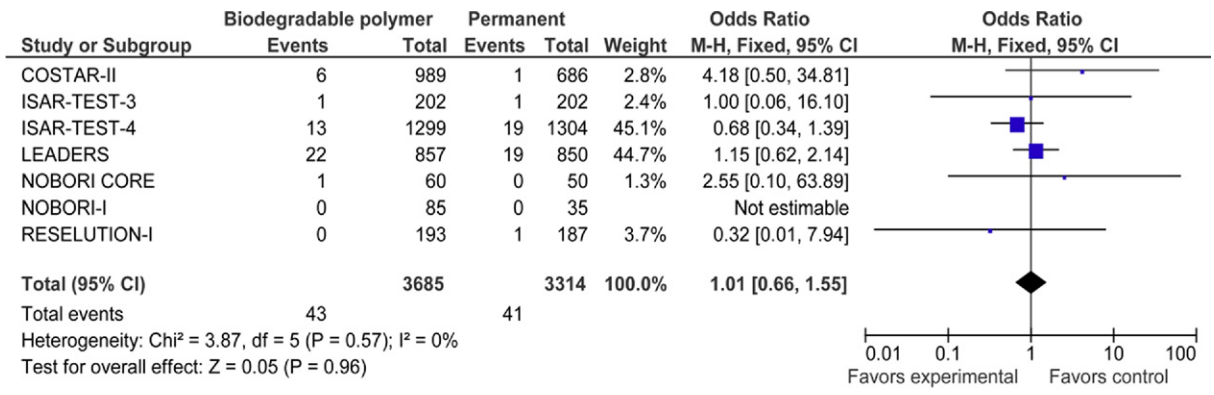

Figure 1 **Effect of Biodegradable Polymer Drug-Eluting Stents on the Risk for Stent Thrombosis During the First Year After Implantation**

Meta-analysis of 7 randomized trials comparing drug-eluting stents with biodegradable versus durable polymers. No difference was found in the rate of stent thrombosis during the first year after implantation (1.2% vs. 1.2%; odds ratio: 1.01; 95% confidence interval: 0.66 to 1.55; p = 0.96).

ResElution-I) (3), including more than 7,000 patients, and found no differences in the rate of stent thrombosis during the first year (1.2% vs. 1.2%; odds ratio: 1.01; 95% confidence interval: 0.66 to 1.55; p = 0.96) (Fig. 1).

Nevertheless, the potential benefits of biodegradable polymers should be evaluated with longer follow-up. In fact, when we analyzed only late (>1 month) stent thrombosis, a 40% relative risk reduction in the rate of stent thrombosis, although not statistically significant, was found in patients allocated to biodegradable polymer stents (0.27% vs. 0.45%, respectively; odds ratio: 0.68; 95% confidence interval: 0.32 to 1.48; p = 0.33).

We believe that biodegradable polymers will contribute to improve the long-term safety of drug-eluting stents, but we will have to wait for evidence from long-term (several years) follow-up in large randomized trials.

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REFERENCES

1. Holmes DR Jr., Kereiakes DJ, Garg S, et al. Stent thrombosis. J Am Coll Cardiol 2010;56:1357–65.
2. van der Giessen WJ, Lincoff AM, Schwartz RS, et al. Marked inflammatory sequelae to implantation of biodegradable and nonbiodegradable polymers in porcine coronary arteries. Circulation 1996;94:1690–7.
3. Windecker S, Serruys PW, Wandel S, et al. Biolimus-eluting stent with biodegradable polymer versus sirolimus-eluting stent with durable polymer for coronary revascularisation (LEADERS): a randomised non-inferiority trial. Lancet 2008;372:1163–73.
4. Salinas P, Moreno R, Sanchez-Recalde A, et al. Drug eluting stents with biodegradable polymer: do they reduce stent thrombosis during the first year after implantation? A meta-analysis of seven randomized trials. Available at: http://circ.ahajournals.org/cgi/content/meeting_abstract/122/21_MeetingAbstracts/A11322. Accessed June 18, 2011.

Reply

We appreciate the comments of Dr. Salinas and colleagues regarding our paper (1). The safety of new-generation stents is improving. This may be the result of several factors, one of which may be the use of "biodegradable" polymers; other factors may also be as important, including improved antiplatelet therapy, longer duration of antiplatelet therapy, and improved initial stent placement using high-pressure balloons or guidance with intravascular ultrasound and/or optical computed tomography. Of interest, in the authors' meta-analysis, there were 43 patients in the biodegradable group and 41 in the permanent polymer group. The numbers are therefore small, although any event is often catastrophic for the individual patient. Given the low incidence of the phenomenon and the changing technology, larger series and longer follow-up will be needed, although challenging. At the present time, a randomized trial with stent thrombosis as the primary end point is unavailable for study.

We also appreciate the comments of Prof. Kounis regarding Kounis syndrome. There are multiple issues involved in stent thrombosis. Some issues relate to the underlying coronary artery disease, some to the specific stent design, including bare-metal versus drug-eluting stents, and for drug-eluting stents in particular the specific polymer and drug or drugs used. In addition, there are issues of compliance with and response to dual-antiplatelet therapy. Findings consistent with hypersensitivity have been seen in some autopsy series, as mentioned by Prof. Kounis, and may play a role. Continuing ongoing experience with polymer-free designs as well as different drugs may help resolve some of the issues. Fortunately, the incidence of this often catastrophic complication is very low; this very fact makes reaching definitive evidence-based conclusions about preventive strategies challenging.

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REFERENCE

1. Holmes DR Jr., Kereiakes DJ, Garg S, et al. Stent thrombosis. J Am Coll Cardiol 2010;56:1357–65.

Doing the Right Thing

I could not agree more with "minding the gap" between performance measures and the practice of medicine (1). Having been in the position of starting a new heart failure (HF) program over the past 4 years, I have experienced firsthand the push and pull of meeting measures versus "doing the right thing" for the patient, which sometimes are in alignment but not always. I recently looked at our hospital's data and found that despite steady improvement in adherence to the "all or none bundle" for the 4 hospital discharge measures for HF, there was no change in 30-day readmission rates over a 5-year period (2). When improvements in outcomes have been shown in other studies, the association between measures and outcomes seems much more likely related to "other things" that were not captured, rather than adherence to the current measures per se (with the possible exception of angiotensin-converting enzyme inhibitors/angiotensin receptor blockers for low left ventricular ejection fraction). Some of those "other things" could include the handoff at discharge and need for close follow-up, although elucidating the most important elements to prevent morbidity and mortality following a hospitalization for HF has proven to be elusive. A particular pet peeve of mine has always been the "smoking cessation" measure for HF. This measure not only has never been shown to benefit patients with HF, but previous work in my laboratory with chronic activation of nicotinic receptors in HF dogs might even suggest biologic plausibility for a benefit in HF (3). In the current age of quality and performance measures, it remains most important to "do the right thing" for the patient while the measures are being met, rather than simply focusing on meeting the measures. Additionally, there clearly remains a great need to determine measures that actually are beneficial for individual patients.

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REFERENCES

1. Ghali JK, Massie BM, Mann DL, Rich MW. Heart failure guidelines, performance measures, and the practice of medicine: mind the gap. J Am Coll Cardiol 2010;56:2077–80.
2. Dunlap ME, Greco PJ, Halliday BL, Einstadter D. Lack of correlation between HF performance measures and 30-day rehospitalization rates (abstr). J Card Fail 2009;15:283.
3. Bibevski S, Dunlap ME. Prevention of diminished parasympathetic control of the heart in experimental heart failure. Am J Phys 2004;287:H1780–5.

Reply

We are delighted that Dr. Dunlap shares our views (1), and we appreciate the emphasis he places on the need for a careful selection of performance measures. His observation on the lack of correlation among patients with heart failure between steady improvement in adherence to performance measures and 30-day readmission rates over a 5-year period is noteworthy. The recently published data from the Veterans Affairs Health Care System document a divergence between 30-day rehospitalization for heart failure and survival among 50,125 patients with first hospitalization for heart failure (2). Over a 4-year period, mortality at 30 days decreased, whereas the number of rehospitalizations for heart failure increased, highlighting the potential peril of using hospital readmission as a performance measure (3).

We are less concerned, however, about choosing smoking cessation counseling as a performance measure. We agree with Dr. Dunlap that no controlled clinical trial has documented the benefit of such an approach in patients with heart failure. On the other hand, smoking cessation is not associated with potential harm. One of our major concerns in converting guideline recommendations into performance measures is the potential for harm that results from exposing a large population of patients with heart failure to pharmacological and device therapy without adequate assessment of the risk/benefit ratio (1). No such concern exists for smoking cessation counseling.

An important limiting feature of smoking cessation counseling as a performance measure is that it could be "checked" as having been performed when no actual intervention was delivered. The drive and incentives to achieve high scores on performance measures encourage efforts that focus on ensuring that documentation of compliance with smoking cessation counseling was recorded, whether or not such counseling was provided.

In conclusion, we are in complete agreement with Dr. Dunlap that we should "'do the right thing' for the patient while the measures are being met, rather than simply focusing on meeting the measures."

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REFERENCES

1. Ghali JK, Massie BM, Mann DL, Rich MW. Heart failure guidelines, performance measures, and the practice of medicine: mind the gap. J Am Coll Cardiol 2010;56:2077–80.
2. Heidenreich P, Sahay A, Kapoor J, Pham MX, Massie B. Divergent trends in survival and readmission following a hospitalization for heart failure in the Veterans Affairs Health Care System 2002 to 2006. J Am Coll Cardiol 2010;56:362–8.
3. Axon NR, Williams MV. Hospital readmission as an accountability measure. JAMA 2011;305:504–5.